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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,900	02/08/2002	Peter H. St. George-Hyslop	1034/1F810US2	2710

7590 01/13/2005

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,900	ST. GEORGE-HYSLOP ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 29, 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-23* is/are pending in the application.

4a) Of the above claim(s) *18-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Office Action is in response to the paper filed November 29, 2005. Claims 1-6 has been canceled. Claims 18-23 have been withdrawn from further consideration by the Examiner because these Claims are drawn to non-elected inventions. Claims 7-17 are currently under examination.

Priority is set to January 9, 1998.

Withdrawal of Objections and Rejections

The objection to the disclosure is withdrawn.

Maintenance of Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-17 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 7, it is not clear what a normal presenilin protein looks like, and therefore what a mutant presenilin protein would look like relative to this sequence. In Claims 12-15, there is no reference sequence provided to know which amino acid residues are defining the armadillo binding fragment. **That is**, recitation that the mutant presenilin comprises amino acid residues 260-409 of the mutant presenilin does not define the sequence, even if a reference wild-type sequence is provided. What are the mutations? Do the mutations share 90% identity to the wild-type, for example? The term "mutant presenilin" is so broad that it encompasses any polypeptide that binds to the armadillo protein because one skilled in the art can easily add, delete, and substitute amino acids in presenilin to arrive at any polypeptide.

Further, these amino acid residue positions are stated to be a mutated, thus further rendering the claim indefinite because the mutant sequence is not provided. Mutant proteins can comprise substitutions, deletions, and additions. Therefore, the amino acid positions set forth in the claims are "moving targets", depending on the mutant presenilin protein sequence.

In Claim 9, the acronym hNPRAP is not defined. It appears that it is intended that this acronym stands for human neural plakophilin-related armadillo repeat protein, but this definition does not appear to be set forth in the specification. Applicants may wish to provide prior art evidence of the definition of hNPRAP to establish that this acronym is well-known and can be placed in the specification and claims without adding new matter.

The control group of Claim 17 does not appear to have antecedent basis in Claim 7. Claim 7 requires a culture of cells that express armadillo protein and mutant presenilin. Therefore, the control group must also comprise culture of cells that express armadillo protein and mutant presenilin or there can be no comparison between the two cultures regarding the activity of the test substance. If the control group comprises wild-type presenilin, then there can be no comparison of the activity of the test substance between two different cultures.

Applicants urge that the term "mutant presenilin protein" is not indefinite because one skilled in the art would know that it is wild-type presenilin with a mutation. Allelic variants are also mutants of each other. Also, how many mutations and what kind, where will these mutation be? As noted in the rejection above, this term is so broad that the mutant may only share a small (or no) percentage identity to presenilin.

Applicants have added a reference wild-type sequence to Claims 12-15 and believe that this amendment overcomes this rejection. The reference wild-type sequence does not provide any hint of what the mutant presenilin will look like – see the rejection above for the discussion of this issue.

Applicants have provided a reference for the term hNPRAP acronym found in Claim 9. As noted above, this is an acronym and renders the claim indefinite. The Examiner has offered the solution in this and the previous Office Actions: Applicants may wish to provide prior art evidence of the definition of hNPRAP to establish that this acronym is well-known and can be placed in the specification and claims without adding new matter.

Applicants state that a control group is found in Claim 7, thus providing antecedent basis for the control group of Claim 17. The rejection should be reviewed. The control group of Claim 7 CANNOT comprise the wild-type presenilin and armadillo protein. To be a control group in Claim 7, the control group must comprise the mutant presenilin and armadillo protein because it is what is used to identify substances that modulate nuclear translocation of armadillo protein. Therefore, the test group is mutant presenilin and armadillo protein with the test substance, and the control group is mutant presenilin and armadillo protein without the substance. Having a control group comprising wild-type presenilin and armadillo protein says nothing about what is happening with the mutant presenilin and test substance. Thus, the control group of Claim 17 has no antecedent basis in Claim 7.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the

date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER